

**FOOD AND DRUG ADMINISTRATION (FDA)**

Center for Drug Evaluation and Research (CDER)

***Antimicrobial Drugs Advisory Committee (AMDAC) Meeting***

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

October 16, 2019

**QUESTIONS**

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1. **DISCUSSION:** Please discuss your evaluation of the mortality imbalance observed in the CREDIBLE-CR study with respect to the overall risk benefit assessment for cefiderocol and provide recommendations for labeling and/or the need for additional studies.
  
2. **VOTE:** Has the Applicant provided substantial evidence of the efficacy and sufficient evidence of the safety of cefiderocol for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis in patients with limited or no alternative treatment options?
  - a. If yes, please provide any recommendations concerning labeling.
  
  - b. If no, what additional studies/analyses are needed?